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AUG 16 2006

REMARKS:

Applicant has carefully studied the non-final Examiner's Action mailed May 16, 2006. These explanatory remarks are believed to be fully responsive to the Action. Accordingly, this important patent application is now believed to be in condition for allowance.

Claim Rejections 35 U.S.C. § 102

Applicant acknowledges the quotation of 35 U.S.C § 102(e).

Claims 1, 2, 6, 8, 10, 21, 22 and 24-28 stand rejected under 35 U.S.C. 102(e) as being anticipated by U.S. 6,678,558 B1 (Dimmer et al.).

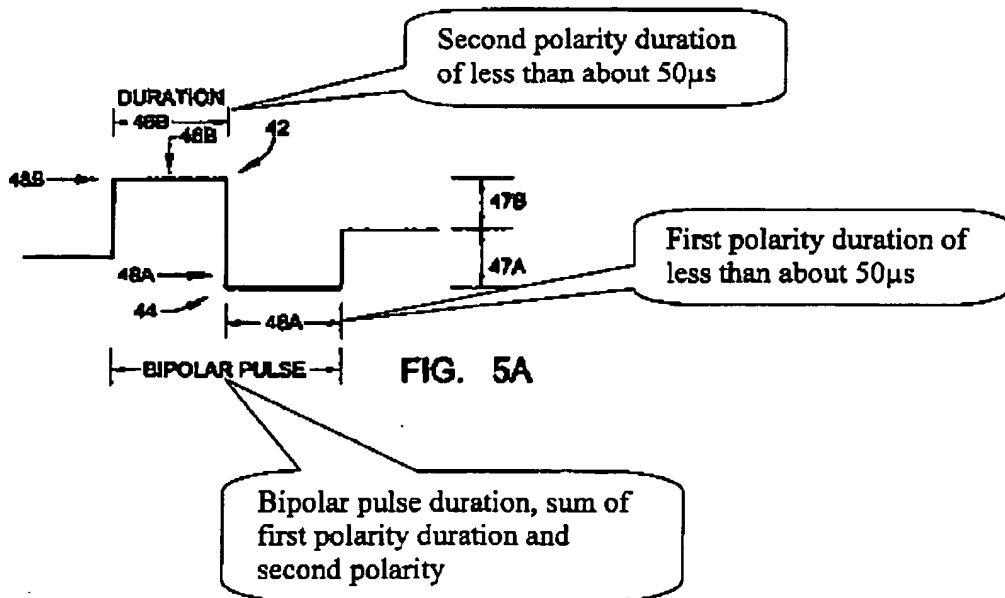
The Office states that Dimmer teaches a method for facilitating the delivery of a desired molecule into a target tissue consisting essentially of introducing a molecule into a target tissue comprising a cell, applying an electric field to the target tissue wherein the application of the electric field consists of a single continuous electric field (claims 1, 21) or a plurality of substantially continuous electric fields (claim 24) in the range of 1mV/cm to 200V/cm applied for a duration of 200ms to 20 minutes and effecting a change in porosity of the cell in the target tissue in response to the application of the electric field wherein the change in porosity is sufficient to facilitate entry of the desired molecule into the cell (claims 1, 21, 24); wherein the duration of the applying step is in the range of 200ms to 100 sec (claims 2 and 22); wherein the electric field comprises a pulse comprising a combination of at least two of the indicated pulse waveforms (claim 26); wherein the injection step is by syringe injection (claims 8, 24); wherein the target tissue is skin or tumor tissue (claims 10, 28).

More specifically, the Office states that Dimmer et al. teaches a method for delivering an agent such as a nucleic acid into a cell of a target tissue (such as skin or tumor tissue) using an electric signal that has a bipolar waveform (e.g., see abstract), wherein the agent is injected directly by needle and syringe (e.g., see column 2 lines 24-27), wherein the electric signal can have a bipolar, square or sinusoidal waveform (e.g., see column 5, lines 35-36; column 8, lines 17-30), wherein the electric signal can be a plurality of electric signals (e.g., see column 9, lines 10-16) wherein the electric field(s) are in the range of 1mv/cm to 200V/cm (e.g., 25V/cm or 100V/cm see column 10, lines 29-42); wherein the electric field is applied for a duration of 200ms-20 minutes (e.g., most preferably about 50µs-400ms see column 10, lines 54-60; column 13, lines 7-19; column 14, lines 21-23; column 23, lines 1-11; column 24, lines 43-50; column 29, lines 12-15; claims 1, 10, 11, 16, 17, 25).

Applicant respectfully disagrees with the finding of the Office.

Claims 1, 21 and 24 of the present invention describe the application of a “continuous electric field in the range of 1mV/cm to 200V/cm applied for a duration of 200ms to 20 minutes”. As such, a continuous electric field of the present invention is a pulse in the range of 1mV/cm to 200V/cm and applied for a duration of 200ms to 20 minutes.

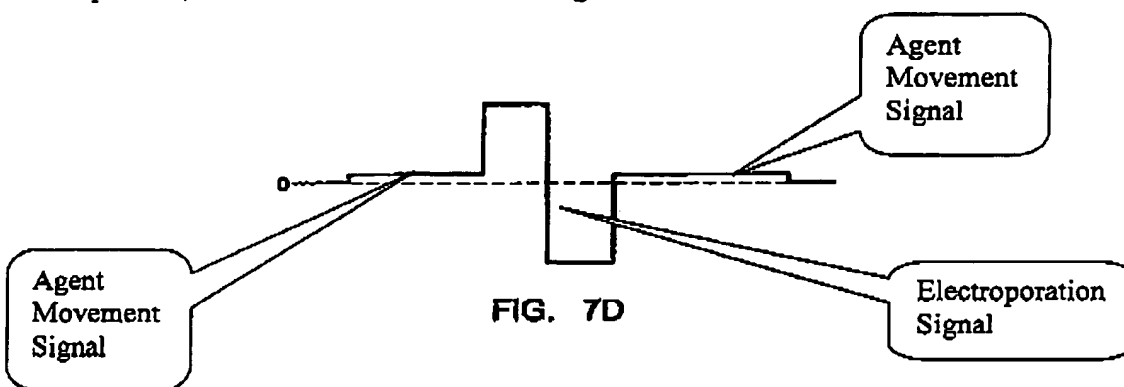
Dimmer describes at col. 10, lines 54-60, a “total electroporation signal duration” as being applied for a duration that is preferably less than about 10 seconds, more preferably about 30µs – 10 seconds, even more preferably about 30µs – 1ms and most preferably about 50µs – 400ms. As such, the Office has concluded that the range of 50µs – 400ms for the “total electroporation signal duration” of Dimmer falls within the range of 200ms – 20 minutes as claimed by the present invention. Dimmer also states that the “total electroporation signal duration” is the sum of the first polarity durations and the second polarity durations of each electroporation signal included in a single electroporation therapy treatment. As such, the “total electroporation signal duration of between 200ms and 20 minutes” as described by Dimmer consists of at least one bipolar pulse having a first polarity and a second polarity. Dimmer describes a bipolar pulse at col. 6, lines 17-48, and with reference to Fig. 5A. Dimmer states that the first polarity duration 46A and the second polarity 46B make up the bipolar pulse duration which is described by Dimmer and identified by the Office to fall within the claimed range of between 200ms and 20 minutes. As such, the “total electroporation signal duration” as described by Dinner is not equivalent to the “continuous electric field applied for a duration of 200ms to 20 minutes” as disclosed and claimed by the present invention because the total electroporation signal duration of Dimmer includes at least one bipolar pulse having at least two different polarity signals which would not be considered a continuous electric field as claimed by the present invention.



Dimmer states at col. 10, lines 11-20, that the therapeutic electrical signals according to the present invention preferably have a pulse duration of less than about $50\mu\text{s}$, more preferably have a pulse duration of less than about $12.5\mu\text{s}$ and most preferably a pulse duration of less than about $5\mu\text{s}$. As can be seen with reference to Fig. 5A, Dimmer describes a continuous pulse having a specific voltage level that is applied for a duration of less than about $50\mu\text{s}$. As such, the pulse described by Dimmer as being a single continuous electric field is applied for a duration of less than about $50\mu\text{s}$.

By contrast, the present invention describes the application of a single continuous electric field in the range of 1mV/cm to 200V/cm applied for a duration of 200ms to 20 minutes. Accordingly, a single continuous electric field as described by Dimmer is applied for a duration of less than about $50\mu\text{s}$, while the present invention claims the application of a single continuous electric field for a duration of between 200ms to 20 minutes.

The Office additionally cites col. 14, lines 21-23 of Dimmer as teaching the single continuous electric field of the present invention being delivered for a duration of between 200ms and 20 minutes. However, at col. 14, lines 21-23, Dimmer describes an agent movement signal having a potential of about 5V - 200V and more preferably about 10V - 100V , having a duration of the agent movement signal of preferably about $100\mu\text{s}$ - 10 seconds. However, Dimmer describes the agent movement signal at col. 8, lines 48-55, and col. 9, lines 1-18, as being effective in moving the agent relative to the cells. This movement increases the opportunity for an agent to enter a cell through a pore created by the electroporation signals. As such the agent movement signal as described by Dimmer is not used for electroporation, but instead for movement of the agent towards the cells.



The present invention claims applying an electric field to the target tissue wherein the application of the electric field consists of a single continuous electric field (claims 1, 21) or a plurality of substantially continuous electric fields (claim 24) in the range of 1mV/cm to 200V/cm applied for a duration of 200ms to 20 minutes and effecting a change in porosity of the cell in the target tissue in response to the application of the electric field wherein the change in porosity is sufficient to facilitate entry of the desired molecule into the cell. As such, the single continuous electric field of the present invention effects a change in porosity of the cell in the target tissue.

By contrast, the agent movement signal as described by Dimmer does not effect a change in porosity of the cell in the target tissue, but is only effective in moving the agent closer to the cell that is being targeted by the electroporation signals. Accordingly, the agent movement signal as described by Dimmer does not anticipate a continuous electric field in the range of 1mV/cm to 200V/cm applied for a duration of 200ms to 20 minutes and effecting a change in porosity of the cell in the target tissue in response to the application of the electric field wherein the change in porosity is sufficient to facilitate entry of the desired molecule into the cell as disclosed and claimed by the present invention.

For the reasons stated above, Applicant believes that independent claims 1 and 21 are not anticipated by Dimmer et al. and are believed to be in condition for allowance. More specifically, neither the "total electroporation signal" or the "agent movement signal" of Dimmer anticipate the continuous electric field in the range of 1mV/cm to 200V/cm applied for a duration of 200ms to 20 minutes and effecting a change in porosity of the cell in the target tissue in response to the application of the electric field wherein the change in porosity is sufficient to facilitate entry of the desired molecule into the cell as disclosed and claimed by the present invention.

Claims 2, 6, 8 and 10 are dependent upon claim 1, and are therefore allowable as a matter of law. Claims 22 and 24-28 are dependent upon claim 21, and are therefore allowable as a matter of law.

By cancellation or amendment of these claims, applicants only wish to advance prosecution of the present application. Applicants reserve the right to prosecute one or more subject matter in the original claims in one or more continuation applications and that equivalence to these claims have not been relinquished by these amendments.

If the Office is not fully persuaded as to the merits of Applicant's position, or if an Examiner's Amendment would place the pending claims in condition for allowance, a telephone call to the undersigned at (813) 925-8505 is requested.

Very respectfully,
SMITH & HOPEN



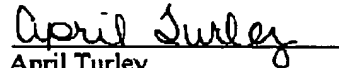
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Attorneys for Applicant

Dated: August 16, 2006
Reg No. 46,457

CERTIFICATE OF FACSIMILE TRANSMISSION
(37 C.F.R. 1.8(a))

I HEREBY CERTIFY that this Amendment I is being transmitted by facsimile to the United States Patent and Trademark Office, Central Fax Center, Art Unit 1635, Attn: Jon E. Angell, (571) 273-8300 on August 16, 2006.

Dated: August 16, 2006


April Turley